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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,034	04/23/2001	Gerardo Castillo	PROTEO.P07CI3	4033

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/786,034	CASTILLO ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 20-25 are presented for examination.

Applicant's Amendment filed January 8, 2007 has been received and entered into the present application.

Claims 20-25 remain pending and are under examination. Claims 20-25 are amended.

Applicant's arguments and amendments to the claims, filed January 8, 2007, have been fully considered. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 20, 22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Hastings et al. (U.S. Patent No. 6,224,871; Issued 2001, Filed March 1998).

Hastings et al. teaches dietary compositions for promoting healthy joint function comprising a herbal blend, which comprises, gingko biloba, cat's claw powder (*Uncaria tomentosa*), bilberry extract, and aloe vera extract, wherein the herbal blend may optionally be combined with a dietary supplement that contains ashwagandha, also known as Indian ginseng (col.3, l.35-45), and further wherein the disclosed compositions may be administered to a subject orally. Please reference column 1, line 61-column 2, line 18; column 4, lines 50-58; column 5, lines 35-41 and Examples 1-2 at columns 4-5.

Though Hastings et al. does not explicitly teach the administration of the disclosed composition for the reduction, disruption, dissolution or inhibition of amyloid fibrils (see present claim 22), such a limitation is an intended use of the composition and fails to impart any physical or material characteristic to the composition that would not already be present in the prior art composition of Hastings et al.

Additionally, in light of the fact that Hastings et al. teaches a pharmaceutical composition of identical components to that presently claimed, the amyloid inhibitory activity or efficacy that Applicant presently claims is necessarily present in the composition disclosed by Hastings et al. As taught by the MPEP, products of identical composition cannot have mutually exclusive properties. Please reference MPEP §2112.01.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

As previously stated in the prior Office Action dated October 5, 2006, Applicant's declaration executed under 37 C.F.R. 1.131(b) to overcome the previous application of Hastings et al. as prior art has been noted, but is insufficient. In particular, Applicant has failed to establish that conception of the presently claimed invention occurred prior to the effective date of the Hastings et al. reference (March 11, 1998). It appears from Applicant's declaration that conception of the claimed invention occurred after the 102(e) filing date of the Hastings et al. reference. The statements in paragraph (4), which pertain to the inventive compositions of the instant application, appear to indicate that conception occurred sometime between May 15, 1998 and August 30, 1998, which is after the effective filing date of Hastings et al. Moreover, the declaration does not establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Hastings et al. patent. Accordingly,

constructive reduction to practice for the instant invention appears to have been when the provisional application was filed (August 30, 1998), which is after the filing date of Hastings et al.

As stated in 37 C.F.R. 1.131(b), "The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or to photocopies thereof, must accompany and form part of the affidavit or declaration or their absence must be satisfactorily explained." Applicant has failed to provide any original exhibits or evidence in support of their assertion that conception of the presently claimed invention occurred prior to the filing date of Hastings et al. While the absence of evidence in the record is not, in and of itself, grounds to dismiss a claim that conception occurred prior to a cited reference, Applicant has failed to provide any explanation as to why such evidence was not otherwise presented to the Office.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. (U.S. Patent No. 6,224,871; Issued 2001, Filed March 1998) in view of Hsia et al. (U.S. Patent No. 5,976,548; Issued 1999, Filed 1997).

Hastings et al. teaches dietary compositions for promoting healthy joint function comprising a herbal blend, which comprises, gingko biloba, cat's claw powder (*Uncaria tomentosa*), bilberry extract, and aloe vera extract, wherein the herbal blend may optionally be combined with a dietary supplement that contains ashwagandha, also known as Indian ginseng (col.3, l.35-45), and further wherein the disclosed compositions may be administered to a subject orally. Please reference column 1, line 61-column 2, line 18; column 4, lines 50-58; column 5, lines 35-41 and Examples 1-2 at columns 4-5.

Though Hastings et al. does not explicitly teach the administration of the disclosed composition for the reduction, disruption, dissolution or inhibition of amyloid fibrils (see present claims 22-23), such a limitation is an intended use of the composition and fails to impart any physical or material characteristic to the composition that would not already be present in the prior art composition of Hastings et al.

Additionally, in light of the fact that Hastings et al. teaches a pharmaceutical composition comprising cat's claw, the amyloid inhibitory activity or efficacy that Applicant has presently attributed to the plant matter obtained from the plant *Uncaria tomentosa* (i.e., cat's claw) is necessarily present in the composition disclosed by Hastings et al. As taught by the MPEP, products of identical composition cannot have mutually exclusive properties. Please reference MPEP §2112.01.

Hsia et al. teaches nutritional supplements for the human diet for, e.g., strengthening connective and structural tissues (see col. 2, l.66-col.3, l.5). Hsia et al. teaches nutritional supplements comprising ginseng, vitamin E, selenium, niacinamide, folate, vitamin B12 and choline (see Example 1, Table bridging columns 13-14).

One of ordinary skill in the art would have been motivated to combine the composition of Hastings et al. with the composition of Hsia et al. because the composition of Hastings et al. was known to promote healthy joint function and the composition of Hsia et al. was known to strengthen connective and structural tissues, tissues which are known to be integral components of human joints. In other words, each composition was known in the prior art to have joint health enhancing effects. The very fact that each was known in the art to have the same therapeutic utility raises the reasonable expectation of success that the two compositions, when combined, would have, at minimum, additive, if not synergistic, joint health promoting effects when combined.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960)."

Response to Applicant's Arguments

Applicant alleges that neither Hastings nor Hsia teach the claimed invention, nor does they teach that modifications of their respective supplements are either necessary or desirable. Applicant further asserts that the skilled person must reasonably question which individual components of Hsia's composition would have efficacy in promoting joint health as opposed to efficacy for decreasing glucose concentration when combined with Hastings. Applicant submits that the skilled person would not have had a reasonable expectation of success without undue experimentation or direction from the prior art.

Applicant's arguments have been fully and carefully considered in their entirety, but fail to be persuasive.

First, it is noted that Hastings et al., in fact, does teach the claimed invention as presently claimed in Applicant's instant claims 20, 22 and 24. Please see the rejection set forth *supra* under 35 U.S.C. 102(e).

Second, the fact that neither Hastings et al. nor Hsia et al. specifically teach the necessity or desirability of modifying their respective supplements is immaterial to the fact that the prior art provides an implicit motivation to make such a combination, due to that fact that each composition was known for the same therapeutic purpose. Applicant is reminded that an express motivation to combine is not required to be explicitly stated in the prior art in order to construct a finding of obviousness. Please reference MPEP §2145(X), which states, "However, there is no requirement that an express, written motivation to combine must appear in the prior art references before a finding of obviousness." Here, in the instant case, the desirability of combining the compositions of both Hastings et al. and Hsia et al. is clearly supported by the fact that each was known in the art for the same therapeutic purpose and, thus, the skilled artisan would have reasonably expected at least additive, if not synergistic, joint health enhancing effects when combined. Please see the rejection *supra* under 35 U.S.C. 103(a).

Third, though Applicant alleges a need for the skilled artisan to undertake undue experimentation to determine which components of the composition disclosed by Hsia et al. would have efficacy in promoting joint health and which would have efficacy in decreasing glucose concentration, the teachings of Hsia et al. clearly dictate that the disclosed compositions may be used for *any* of the stated therapeutic purposes with a reasonable expectation of success. Accordingly, a burden of undue experimentation would not have been placed upon the skilled artisan to make such a determination, because Hsia et al. explicitly teaches that the compositions taught within the reference may be used for any of the disclosed therapeutic purposes with a reasonable expectation of equivalent efficacy in achieving the disclosed therapeutic purpose. It is not necessary to know the identity of those components that give the composition its joint health enhancing effects; rather, it is the very fact that the composition *as a whole*

has such effects that is relevant to the instant case.

Further, absent any factual evidence to the contrary presented by Applicant, the cited references clearly provide a reasonable expectation of achieving an enhanced therapeutic effect on joint health by combining the compositions of Hastings et al. and Hsia et al.

For these reasons, rejection of claims 20-25 under 35 U.S.C. 103(a) remains proper and is **maintained**.

Double Patenting (New Grounds of Rejection)

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5, 10-13 and 44-55 of U.S. Patent Application No. 10/610,346.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference

claims.

Although the conflicting claims are not identical, the claims of the instant application and those of the '346 application are not considered to be patentably distinct from each other because the present claims clearly render the copending claim obvious.

The present claims clearly provide for pharmaceutical compositions or agents for the reduction, disruption, dissolution or inhibition of amyloid fibrillogenesis that comprise plant matter from the plant *Uncaria tomentosa*. Though the copending claims are directed to certain sources of the plant matter, such as a commercially available source or an extract of the plant, the present claims are considered to be inclusive of *Uncaria tomentosa* as it is obtained via any available source.

Though the copending claims are directed towards specific amounts or dosage formulations of the claimed plant matter, the determination of the optimum amounts or dosage formulations of the active agent would have been a matter well within the purview of, and *prima facie* obvious to, one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the amounts or dosage formulations that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific amounts or formulations are not seen to be inconsistent with that which would have been determined by, and well within the routine skill of, the skilled artisan.

In addition, the concentration of the active ingredient is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum of workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual

evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s).

Additionally, it is noted that the inhibitory activity of the plant matter is a characteristic intrinsic to the plant matter and is, therefore, considered to be necessarily present in the instant composition that comprises plant matter from the same plant, i.e., *Uncaria tomentosa*. As stated in the MPEP, identical compounds cannot have mutually exclusive properties.

Accordingly, rejection of claims 20-25 of the present application is deemed proper over claims 1, 3-5, 10-13 and 44-55 of U.S. Patent Application No. 10/610,346 as claiming an obvious and unpatentable variant.

Conclusion

Rejection of claims 20-25 remains proper and is **maintained**.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Reyds
Patent Examiner
Art Unit 1614

March 21, 2007

3/24/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER